HEALTH AND SENIOR SERVICES

DIVISION OF FAMILY HEALTH SERVICES

Newborn Screening Program

Newborn Hearing Screening

Proposed Repeal and New Rules: N.J.A.C. 8:19-1

Authorized By: Clifton R. Lacy, M.D., Commissioner,
Department of Health and Senior Services

Authority: N.J.S.A. 26:2-103.1 et seq., particularly 26:2-103.9

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN2004-377

Submit comments by January 14, 2005 to:

Gloria Rodriguez, D.S.W., Director
Special Child Health and Early Intervention Services
Division of Family Health Services
Department of Health and Senior Services
P.O. Box 364
Trenton, NJ 08625-0364

The agency proposal follows:

Summary

The Department is proposing to repeal Subchapter 1 of N.J.A.C. 8:19, Newborn Screening Program, and proposing new rules in its place because of the passage of new legislation, P.L. 2001, c. 373. This legislation mandates that the Department issue guidelines to ensure all newborn children in the State shall be screened for hearing loss. Also, there have been extensive changes within the program following national Early Hearing Detection and Intervention standards (for example, www.cdc.gov/ncbddd/ehdi/nationalgoals.htm); advancements in audiologic technology specifically designed for the detection of hearing loss in the newborn period; and advances in knowledge regarding the impact of hearing loss on the development of speech and language acquisition, cognitive, social and emotional skills and the effect of early intervention services by six months of age. The purpose of Chapter 19 is to constitute the rules governing the implementation of N.J.S.A. 26:2-103, 26:2-110 and 26:2-111.

In 1969, the Joint Committee on Infant Hearing (JCIH) was established and is currently comprised of representatives from the American Academy of Pediatrics, the American Academy of Otolaryngology and Head and Neck Surgery, the American Speech Language Hearing Association, the American Academy of Audiology, the Council on Education of the Deaf, and Directors of Speech and Hearing Programs in State Health and Welfare Agencies. The JCIH's primary activity has been publication of position statements summarizing the state of the science and the art of infant and child hearing screening, and

recommending the preferred practice in early identification and appropriate intervention of newborns and infants at risk for or with hearing loss.

The JCIH has published six position statements since 1969, the most recent in 2000. The Department proposes to adopt, as the State standard for early hearing loss detection and intervention (EHDI) for infants and for monitoring infants with risk factors for progressive or late-onset hearing loss, the recommendations the JCIH articulated in its "Year 2000 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs," as amended and supplemented (JCIH Position Statement).

The Department understands that the JCIH anticipates the imminent publication of an update to the 2000 position statement. If the JCIH publishes an updated position statement prior to the adoption of the proposed new rules, the Department anticipates making technical amendments upon adoption to reflect the incorporation by reference of the updated version, as amended and supplemented.

The JCIH, through its position statements, endorses early hearing loss detection and intervention (EHDI) for infants through integrated, interdisciplinary state and national systems of universal newborn hearing screening (UNHS), evaluation, and family-centered intervention. Following is a description of the JCIH position statement.

Part I contains a description of the historical background of EHDI programs and the current state of UNHS. Part II contains a listing of the eight principles that the JCIH endorses as the foundation for effective EHDI systems.

Part III contains the JCIH's recommended guidelines for the development and implementation of successful EHDI systems, in the context of their relationship to the eight principles described in Part II. Subpart IIIA contains the JCIH's recommendations as to the respective roles and responsibilities of the parties interested and involved in EHDI, that is, institutions, agencies, families, and professionals.

Subpart IIIB describes in depth the eight principles listed in Part II for the foundation of an effective EHDI system, and contains recommendations for personnel, program protocol development, screening technologies and protocols, and benchmarks and quality indicators for birth admission hearing screening.

Subpart IIIC contains recommendations for audiologic and medical evaluations that should follow confirmation of hearing loss in infants referred from UNHS, and for benchmarks and quality indicators for the confirmation of hearing loss. Medical evaluations addressed in Subpart IIIC include the roles of pediatricians, primary care physicians, otolaryngologists and other medical specialists.

Subpart IIID addresses early intervention, and contains recommendations for the development of effective early intervention programs by reference to six principles. The subpart contains recommendations for audiologic habilitation, medical and surgical intervention, communication assessment and intervention, and benchmarks and quality indicators for early intervention programs.

Subpart IIIE identifies specific risk indicators for delayed onset hearing loss, and contains recommendations for continued surveillance of infants and

toddlers who present with these risk factors. Practitioners' attention to and familiarity with this subpart is important for compliance with the proposed new rules at N.J.A.C. 8:19-1 because the proposed new rules would require adherence to these recommendations for continued surveillance, such as the reevaluation intervals for patients who present with the risk factors described therein.

Subpart IIIF contains recommendations for the protection of infants' and families' rights with respect to access to UNHS including access to financial options, deference to family and consumer-oriented language in the provision of information necessary to informed consent, choice in the acceptance or refusal of initial and follow-up care, and confidentiality in accordance within applicable legal requirements. Subpart IIIG contains recommendations for information infrastructure and management for service providers and for governmental agencies and committees charged with advisory, funding, and regulatory functions.

Part IV describes JCIH's recommendations for future directions for early identification assessment, and intervention for newborns and very young infants with hearing loss.

There is national interest in newborn hearing screening. The JCIH Position Statement recommends that all newborns be screened for hearing loss by one month of age using a physiologic measure. The JCIH, along with the 1993 National Institutes of Health Consensus Statement, advocates the identification of all infants with hearing loss by three months of age and

intervention and treatment by six months of age. With the use of automated Auditory Brainstem Response (ABR) and Otoacoustic Emissions (OAE), hospitals have the tools for objective, efficient, and reliable universal newborn hearing screening. In its statement of February 2, 1999, the American Academy of Pediatrics endorsed the implementation of universal newborn hearing screening.

The proposed new rules maintain universal newborn hearing screening in New Jersey, encourage follow-up programs for those who do not pass initial screens, identify infants that present with risk indicators for late onset or progressive hearing loss, and ensure that they receive periodic audiologic monitoring. The proposed new rules also maintain compliance from hospitals, pediatricians and other health care professionals that provide audiologic care. Undetected hearing loss can lead to impaired development of speech, language, social and emotional skills, and academic failure. Early detection and intervention can significantly reduce developmental delays and academic difficulties.

Subchapter 1 of N.J.A.C. 8:19 currently addresses Newborn Hearing Screening. The current rules have multiple references to the screening of only infants with risk indicators associated with hearing loss. However, pursuant to P.L. 2001, c. 373, all newborns shall be screened for hearing loss. The sections and content of the proposed new rules have been reorganized for clarity. The new rules also more specifically delineate hospital and health care professional roles and responsibilities pursuant to P.L. 2001, c. 373.

Due to extensive changes and reorganization of the proposed new rules, the content of each section as currently codified is not necessarily paralleled.

At proposed new N.J.A.C. 8:19-1.1, the Department proposes to add definitions of the following words and terms used throughout the subchapter: “auditory brainstem response” or “ABR”; “birth attendant”; “birthing center”; “birthing facility”; “Commissioner”; “decibel” or “dB”; “decibels hearing level” or “dBHL”; “decibels normalized hearing level” or “dBnHL”; “Department”; “diagnostic auditory brainstem response measures”; “distortion product otoacoustic emissions” or “DPOAE”; “electronic birth certificate” or “EBC”; “hearing loss”; “JCIH Position Statement”; “medical home”; “midwife”; “newborn”; “Newborn Hearing Follow-up Report”; “Newborn Hearing Lost to Follow-up form”; “New Jersey Early Hearing Detection and Intervention Program” or “EHDI”; “otoacoustic emissions” or “OAE”; “ototoxic drug monitoring procedures”; “ototoxic medication”; “parent”; “physiologic hearing screening measure”; “responsible physician”; “Special Child Health Services Registration”; and “transient evoked otoacoustic emissions” or “TEOAE”;

N.J.A.C. 8:19-1.2 discusses the requirements for distributing hearing literature to parents. Changes from the existing rules are made to require timely provision of materials and to require the Department to furnish all hospitals and birthing centers with materials in languages that are most representative of the New Jersey population.

N.J.A.C. 8:19-1.3 discusses the hospitals’ responsibilities for conducting screening and the content of the universal screening implementation plan in

accordance with P.L. 2001, c.373. Proposed changes from the existing rules include removal of the requirement for signed consent prior to screening, pursuant to P.L. 2001, c.373 mandating Universal Newborn Hearing Screening, though allowance for exemption from testing remains unchanged. This section also addresses the responsibilities when a birth occurs outside of a hospital or birthing center. Changes from the existing rules are made to detail the components to be included in the hospitals' newborn hearing screening implementation plan.

N.J.A.C. 8:19-1.4 discusses infants transferred out of their birthing hospital or birthing center. New provisions are proposed to clarify responsibilities of hospitals and birthing centers.

N.J.A.C. 8:19-1.5 discusses the training and qualifications of screening/testing personnel. Changes proposed to this section from the current rules are the addition of criteria for training of staff and the designation of responsible personnel for oversight of the program.

N.J.A.C. 8:19-1.6 discusses reporting via the Electronic Birth Certificate (EBC) Registration System and the specific information that is requested by the Department.

N.J.A.C. 8:19-1.7 discusses the criteria for exemption from participation in the Universal Newborn Hearing Screening Program. This remains unchanged.

Proposed new N.J.A.C. 8:19-1.8 would establish procedures for monitoring infants with risk factors for progressive or late-onset hearing loss.

The Department proposes to adopt as the State standard for monitoring these infants the recommendations contained in the JCIH Position Statement.

Proposed new N.J.A.C. 8:19-1.8 also would establish requirements for hearing assessment of certain infants and children treated with ototoxic medications, would articulate reporting obligations for physicians and audiologists identifying risk factors for late onset hearing loss, and would require the medical home to advise certain patients' parents of the importance of audiologic monitoring.

N.J.A.C. 8:19-1.9 discusses the procedures for hearing follow-up care. Changes from the existing rules include requirements for notification of parents and responsible physicians of the test results. Time frames by which additional testing is required are now noted. Specific hospital activities aimed at follow-up are now delineated. The proposed new rule also specifies all necessary components of diagnostic testing.

N.J.A.C. 8:19-1.10 discusses the procedures for reporting newborn hearing follow-up to the Department of Health and Senior Services. The proposed new rules now substantially delineate the requirements for reporting the results of follow-up screening/testing.

N.J.A.C. 8:19-1.11 discusses the documenting and reporting of a diagnosed hearing loss. The proposed new rules include additional responsibilities of audiologists and physicians. Time frames are specified and the registration of ear anomalies are delineated.

N.J.A.C. 8:19-1.12 discusses the central newborn hearing registry pursuant to P.L. 2001, c. 373. The proposed new rules include changes to the description of this system, made to maintain consistency with the new legislation. Proposed new N.J.A.C. 8:19-1.13 would articulate that reports to the Department required under proposed N.J.A.C. 8:19-1 would be for the use of the Department and other agencies as designated by the Commissioner, and would be kept confidential. Proposed new N.J.A.C. 8:19-1.13 would specifically identify these reports to be "information relating to medical history, diagnosis, treatment or evaluation" within the meaning of executive order 26, § 4b1 (McGreevey 2002), and, therefore, not "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., particularly 1A-1.1.

N.J.A.C. 8:19-1.14 discusses the non-liability for divulging confidential information. New provisions in this section specify the Department's role in maintaining confidentiality.

Discussions on the Early Hearing Detection and Intervention (EHDI) Program have been held between staff from the program and representatives from all birthing facilities. Formal meetings are held annually with the EHDI personnel from all birthing facilities in the State to discuss the current Newborn Hearing Screening procedures and practices for each individual facility. Quarterly reports are distributed to all hospitals with screening and follow-up rates along with a comparison to statewide rates. Staff from the program has conducted in-service training at hospitals to ensure that all newborns are

screened appropriately and that the hospitals are in compliance with the Department's rules at N.J.A.C. 8:19.

As the Department has provided a 60-day comment period in this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed repeal of and new rules for N.J.A.C. 8:19-1 will benefit all newborns, parents of newborns, hospitals with maternity units, birthing centers, and pediatric health care providers because the proposed new rules will ensure positive outcomes for newborns and their families through universal newborn hearing screening. No infant shall have his or her hearing screened if the parent objects to such screening on the grounds that the screening conflicts with their bona fide religious tenets or practices. Identification of a hearing impairment by three months of age allows for early intervention during the critical language learning period, from birth to three years. Research shows that early detection and initiation of treatment reduces the degree of handicap a child will experience, socially, educationally, and eventually vocationally.

The overall reaction to the new rules should be positive since universal newborn screening has become an accepted standard of care throughout the health care community. The birthing facilities are familiar with the hearing screening reporting elements of the Electronic Birth Certificate Registration System, the risk factors associated with late onset hearing loss, the need for

audiologic follow-up testing and the importance of reminding families of the need for follow-up hearing screening/testing services. Pediatricians are familiar with the national EHDI standards through the American Academy of Pediatrics. By the very nature of their profession, audiologists are well acquainted with the importance of early detection and treatment of hearing loss in children and the recommended clinical guidelines accepted by the American Speech-Language-Hearing Association and the American Academy of Audiology.

Economic Impact

The Newborn Hearing Screening program is effective in reducing developmental delays, promoting speech and language acquisition, and encourages academic success. The cost of early identification and intervention of infants with hearing impairments is less than the cost of special education programs for those children identified later on in childhood due to speech and language delays. If children are identified early, they may be capable of being appropriately educated in a regular mainstream classroom versus in a more expensive residential program. P.L. 2001, c. 373 requires that insurance companies that are subject to State regulations to cover the cost of screening and periodic monitoring for hearing loss. Given the opportunity to develop language and academic skills adequately, children having a hearing impairment can be vocationally competitive and financially independent.

Proposed new N.J.A.C. 8:19-1 would require hospitals and birthing centers subject to the subchapter to incur costs associated with the purchase

and maintenance of hearing screening equipment and associated supplies, and personnel costs for conducting screening. Inasmuch as hearing screening requirements imposed under N.J.A.C. 8:19-1 have existed since the original adoption of this chapter in 1980, most hospitals have already incurred the initial capital outlays for screening equipment to comply with the previous iterations of this chapter. While there were no non-hospital based freestanding birthing centers in New Jersey in past years when this chapter was in effect, there currently are no such facilities in operation. Were such facilities to come into operation again in New Jersey, the proposed new rules would require either that they purchase and maintain hearing screening equipment and associated supplies, or that they write referrals to patients to have the screening conducted at other facilities.

Audiologists conducting screening in accordance with proposed new N.J.A.C. 8:19-1 already possess the equipment required to conduct follow-up screening in accordance with proposed new N.J.A.C. 8:19, inasmuch as this equipment is a necessary requirement for their existing business operations. Proposed new N.J.A.C. 8:19-1 would require audiologists, physicians, and other health care practitioners such as midwives subject to proposed new N.J.A.C. 8:19-1 to incur administrative and mailing expenses such as postage associated with reporting screening results to the Department and registering children diagnosed with permanent hearing loss through 21 years of age with the Special Child Health Services Registry.

Proposed N.J.A.C. 8:19-1.5 would require hospitals and birthing centers either to retain the services of professionals on staff, or otherwise make arrangements with outside providers, to comply with the requirement that they designate a licensed audiologist or physician to provide oversight for the facility's newborn hearing screening program. The cost of these arrangements would depend on the nature of the arrangement the facility elects to implement with the professional, that is, retention of a professional on staff or creation of a relationship with an external provider, the type of professional, and the particular experience of the professional.

Proposed N.J.A.C. 8:19-1.5 would require the hospitals and birthing centers subject to the chapter to ensure that personnel designated to conduct screening are annually evaluated and trained, and that their applicable licensures remain in good standing.

Hospitals and birthing centers may elect to incur these costs or may require the designated licensed personnel to absorb these costs of training and evaluation. This chapter would not impose licensure fees. Maintenance of applicable licensure in good standing and fees associated therewith are existing requirements of the practice of medicine, audiology, and other licensed healthcare professions, under other laws.

Newborn hearing screening and other monitoring under N.J.A.C. 8:19-1 would be billable to patients. N.J.S.A. 26:2-103.7 establishes that the testing and monitoring required under N.J.S.A. 26:2-103.1 et seq., and the rules promulgated thereunder, "is a covered service under the State Medicaid Program." P.L. 2001,

c.373, at §§ 10 through 15 address requirements concerning the coverage by health insurance of screening and testing required under proposed new N.J.A.C. 8:19-1 and N.J.S.A. 26:2-103.1 et seq.

Federal Standards Statement

Currently, there are no Federal standards or requirements that mandate the screening of newborns for possible hearing loss. Therefore, a Federal standard analysis is not required.

Jobs Impact

The Department does not expect that any jobs will be either lost or generated as a consequence of the proposed repeal and new rules.

Agriculture Industry Impact

The proposed repeal and new rules will not have any impact on agricultural industry.

Regulatory Flexibility Analysis

The proposed new rules at N.J.A.C. 8:19-1 would impose reporting, recordkeeping and compliance requirements on hospitals, none of which are small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as employing more than 100 people full-time. The new rules would impose reporting, recordkeeping and compliance requirements on birthing

centers, and certain private practice audiologists, physicians, and other health care practitioners such as midwives, some of which may be small businesses within the meaning of Regulatory Flexibility Act, N.J.S.A. 52:14B -16 et seq.

As stated above in the Economic Impact, there currently are no birthing centers in New Jersey. Were such facilities to resume existence in New Jersey, they could be small businesses subject to the requirements of proposed N.J.A.C. 8:19-1.

The Department anticipates that there are fewer than 20 private physician's offices and fewer than 50 audiologist's offices that could be small businesses and that would be subject to the proposed new rules.

Proposed new N.J.A.C. 8:19-1.3 would require private healthcare practitioners such as physicians and others who may attend a birth, such as midwives, to notify parents of the availability of newborn hearing screening, and to take such action as is needed to facilitate the provision of such screening to the newborn prior to attaining one month of age. Proposed new N.J.A.C. 8:19-1.8(c) would require physicians or audiologists identifying risk factors for late onset hearing loss, in patients up to three years of age, to report the risk factors to the Department and to advise the parents of the need for audiologic evaluation and monitoring in accordance with the JCIH position statement. Proposed new N.J.A.C. 8:19-1.11(d) would require physicians who diagnose hearing loss to notify parents of the importance of certain additional diagnostic assessments and ongoing reevaluation to monitor hearing status and the performance of any prescribed devices such as hearing aids or cochlear implants, and to register

children with hearing loss through 21 years of age with the Special Child Health Services Registry.

Audiologists, physicians, or other personnel designated by birthing facilities to conduct physiologic hearing screening pursuant to proposed new N.J.A.C. 8:19-1.5 would be required to undergo annual competency evaluations on their screening administration and documentation skills, and their adherence to infection control procedures.

To the extent freestanding birthing centers may come to exist again in New Jersey, the proposed new rules would require such facilities to provide parents with literature provided by the Department in accordance with proposed new N.J.A.C.8:19-1.2; to file a plan with the Department as to how the facility intends to ensure the administration of newborn hearing screening in accordance with proposed new N.J.A.C. 8:19-1.3; to comply with applicable responsibilities for ensuring the screening of transferred patients in accordance with proposed new N.J.A.C. 8:19-1.4; to designate screening personnel and ensure their competency evaluations and training are maintained on schedule and to report changes to designated personnel to the Department in accordance with proposed new N.J.A.C. 8:19-1.5,; to report the identified components of the Electronic Birth Certificate to the State Registrar of Vital Statistics in accordance with proposed new N.J.A.C. 8:19-1.6; to document parents' refusal to authorize the conduct of screening on religious grounds in the patient's medical record and with the State Registrar of Vital Statistics in accordance with proposed new N.J.A.C. 8:19-1.7; to provide the notifications and follow-up reminder contacts

and perform the documentation identified in proposed new N.J.A.C. 8:19-1.9 attendant to the conduct of physiologic hearing screening and to make the appropriate patient referrals for diagnostic pediatric audiologic testing and follow-up reminders.

Should birthing centers return to New Jersey, the proposed new rules would require birthing centers that are small businesses subject to the chapter either to retain the services of professionals on staff, or otherwise make arrangements with outside providers, in order to comply with the requirement at proposed new N.J.A.C. 8:19-1.5 that hospitals and birthing centers designate a licensed audiologist or physician to provide oversight for the facility's newborn hearing screening program. As described in the Economic Impact, above, the cost of these arrangements to birthing centers would depend on the nature of the arrangement the facility elects to implement with the professional and other factors.

As described in the Economic Impact, above, proposed new N.J.A.C. 8:19-1 would require birthing centers, audiologists, physicians, and other health care practitioners subject to the chapter such as midwives to incur administrative and mailing expenses such as postage associated with reporting screening results to the Department and registering children diagnosed with permanent hearing loss through 21 years of age with the Special Child Health Registry.

The Department has reduced the impact that birthing centers that are small businesses might otherwise realize, by not requiring that they conduct newborn hearing screening, provided they make appropriate referrals to outside

providers. This would alleviate the cost birthing centers would incur to purchase and maintain audiology screening equipment and attendant supplies.

The proposed new rules would require birthing centers that are small businesses to ensure that newborns are screened and monitored for hearing loss, either in-house or by referral to outside providers. In addition, the proposed new rules would require birthing centers, audiologists, and physicians to report various test results and the identification of risk factors to the Department on forms supplied by the Department. These reporting requirements necessitate administrative and postage expenses associated with completing and mailing the forms. These reports enable the Department to register positive test results into the Special Child Health Services Registry, in accordance with the statutory mandate at N.J.S.A. 26:2-103.6, and as would be implemented by proposed N.J.A.C. 8:19-1.12. Registration of these results into the Registry in turn triggers follow-up activity through county-based Special Child Health Services offices in the counties where patients with or at risk for hearing loss reside. In addition to being mandated by N.J.S.A. 26:2-103.6b, the Department has determined that these reporting requirements are the minimum requirements necessary to ensure the provision of early intervention services as soon as possible to infants and children with or at risk for hearing loss. Early intervention services could include amplification devices, speech therapy, auditory training, sign language classes, parent support groups, and service coordination.

Smart Growth Impact

The proposed repeal and new rules have no impact on the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:19-1.

Full text of proposed new rules follow:

SUBCHAPTER 1. NEWBORN HEARING SCREENING

8:19-1.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

“Auditory Brainstem Response” or “ABR” means a physiologic measure used for detecting unilateral or bilateral hearing loss by measuring the activity of the cochlea, auditory nerve, and auditory brainstem pathways.

“Birth attendant” means a person who attends and assists during the birth of a child.

“Birthing center” means an ambulatory care facility or a distinct part of a facility that is separately licensed as an ambulatory care facility and provides routine prenatal and intrapartal care. These facilities provide care to low-risk maternity patients who are expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth.

“Birthing facility” means a healthcare facility that provides birthing and newborn care services and includes birthing centers.

“Commissioner” means the Commissioner of Health and Senior Services.

“Decibel” or “dB” means a unit of sound intensity, based on logarithmic relationship of one intensity to a reference intensity.

“Decibels hearing level” or “dBHL” means decibel notation used on the audiogram that is referenced to audiometric zero.

“Decibels normalized hearing level” or “dBnHL” means decibel notation referenced to behavioral thresholds of a sample of normal hearing persons, used most often to describe the intensity level of click stimuli used in evoked potential audiometry.

“Department” means the Department of Health and Senior Services.

"Diagnostic Auditory Brainstem Response measures" means:

1. High intensity click stimuli to assess latency and morphology of Waves I, II, and V;
2. Latency-intensity function by air conduction stimuli (and, in the presence of elevated air-conduction thresholds, bone conduction stimuli); and
3. Tone burst thresholds for low and mid-frequency stimuli for each ear.

"Distortion product otoacoustic emissions" or "DPOAE" means responses generated in response to two continuous pure-tones, referred to as "primaries," and occurring at frequencies that relate mathematically to the frequency of the primaries.

"EBC" means the Electronic Birth Certificate or the Electronic Birth Certificate Registration System.

"Hearing loss" means a hearing loss of 30 dB or greater in the frequency region important for speech recognition and comprehension in one or both ears, which is approximately 500 through 4,000 hertz (Hz).

"JCIH Position Statement" means the "Year 2000 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs," of the Joint Committee on Infant Hearing (JCIH), incorporated herein by reference, as amended and supplemented, published in *Pediatrics,* Vol. 106, No.4, at 798 (October 2000), available by writing to the JCIH c/o American Academy of Pediatrics, 141 Northwest Point Blvd., Elk Grove Village, IL 60007-1098, telephone: (800) 433-9016, ext, 4917, email: screening@aap.org, and available

for download in Adobe Acrobat format at http://www.jcih.org/jcih2000.pdf, and at http://www.jcih.org/posstatemts.htm, and available upon request to the Division of Family Health Services of the Department .

"Medical home" means an approach to providing healthcare that is defined by care that is accessible, family-centered, continuous, comprehensive, coordinated, compassionate, and culturally competent.

"Midwife" means a person trained to assist a woman during childbirth.

"Newborn" means a child up to 28 days old.

"Newborn Hearing Follow-up Report" means Department form number SCH-2 with this title, used for reporting outpatient newborn hearing audiologic exam results, which appears at subchapter Appendix A, incorporated herein by reference. The form is available upon request from the EHDI, and can be downloaded from the Department website as a Word document or http://www.state.nj.us/health/forms/sch-2.dot or as an Adobe Acrobat file at http://www.state.nj.us/health/forms/sch-2.pdf.

"Newborn Hearing Lost to Follow-up form" means a Department form with this title that requires the submission of the child and parent names, date of birth, address, phone number, pediatrician name, and the reason the child is lost to follow-up. The form is available upon request from the EHDI.

"New Jersey Early Hearing Detection and Intervention Program" or "EHDI" means the program within the Department that implements the Universal Newborn Hearing Screening program pursuant to P.L. 2001, c. 373. The EHDI

program may be contacted by mail at PO Box 364, Trenton, NJ 08625-0364, or by telephone at (609) 292-5676.

"Otoacoustic emissions" (OAE) means a physiologic measure used for detecting unilateral or bilateral hearing loss by measuring the responses generated within the cochlea by the outer hair cells, by means of either DPOAE or TEOAE. OAE evaluation does not detect neural dysfunction.

"Ototoxic drug monitoring procedures" means the procedures for monitoring patients who are treated with ototoxic medications.

"Ototoxic medication" means a medication that has a toxic action upon the ear resulting in possible hearing loss.

"Parent" means a biological parent, stepparent, adoptive parent, legal guardian or other legal custodian of the child.

"Physiologic hearing screening measure," means the electrical result of the application of physiologic agents by means of either ABR or OAE, and is also known as electrophysiological hearing screening measure, as used in N.J.S.A. 26:2-103.2.

"Responsible physician" means the infant's medical home or the physician that will be providing well child care for the infant.

"Special Child Health Services Registration" means Department form number SCH-0 with this title, used for reporting children with special health care needs, which appears at subchapter Appendix B, incorporated herein by reference. The form is also available upon request from the EHDI. The form can be downloaded from the Department website as a Word document at

http://www.state.nj.us/health/forms/sch-0.dot or as an Adobe Acrobat file at http://www.state.nj.us/health/forms/sch-0.pdf.

“Transient evoked otoacoustic emissions” or “TEOAE” means frequency-specific responses evoked by brief acoustic stimuli, such as clicks or tone bursts, that generally appear up to 20 milliseconds after stimuli are delivered to the ear.

8:19-1.2 Hearing development literature supplied to parents

(a) Upon or prior to the admission of a newborn to a birthing facility in the State, the birthing facility shall provide all parents of the newborn with literature provided by the Department describing the normal development of auditory function and the New Jersey Early Hearing Detection and Intervention Program.

(b) The literature will be designed to provide parents with an understanding of the implications of hearing loss on the development of speech and language and provide information regarding normal auditory response behaviors.

(c) The Department shall furnish the literature to birthing facilities in languages that are most representative of the New Jersey population.

8:19-1.3 Universal newborn hearing screening

(a) All newborns shall have a physiologic hearing screening measure performed prior to discharge from a birthing facility or no later than one month of age. The

birthing facility, audiologist, or physician, as applicable, shall have discretion to determine the type of physiologic hearing screening measure to be used.

(b) If a birth occurs outside a birthing facility, such as at home, and the newborn is not transferred to a birthing facility, then the midwife or responsible physician shall advise the parent of the availability of newborn hearing screening, and take such action as needed so as to facilitate the provision of such screening to the newborn prior to one month of age.

(c) Each birthing facility shall file a plan with the Department in a manner prescribed by the Commissioner detailing how the birthing facility will implement the newborn hearing screening requirements by January 31st of each year. The plan shall include, at a minimum:

1. The physiologic hearing screening measure to be performed;
2. The time frame after birth that the initial screening is to be performed;
3. The qualifications of and training received by personnel designated to perform the physiologic screening measure;
4. The establishment of quality assurance protocols to determine and evaluate the effectiveness of the program in ensuring that all newborns are screened for hearing loss;
5. The month designated for annual calibration of hearing screening equipment;
6. The name of the licensed audiologist or physician designated pursuant to N.J.A.C. 8:19-1.5(a);

7. Guidelines for the provision of follow-up services for newborns who do not pass inpatient audiologic screening, who are not screened prior to nursery discharge and/or who are at risk for developing a late onset hearing loss;
8. The educational and counseling services to be provided to the parents of newborns identified as having, or being at risk for developing, hearing loss;
9. The guidelines for entering hearing screening results and risk factors for late onset hearing loss into the EBC system;
10. The protocol to be followed to ensure the confidentiality of any patient-specific information to be reported to the Department pursuant to this chapter; and
11. Ototoxic drug monitoring procedures for infants and children under the age of three who are admitted to the hospital for medical conditions that require administration of ototoxic medication.

(d) Infants who are too medically unstable to undergo screening by one month of age shall be tested when medically cleared and before discharge to home.

8:19-1.4 Transferred infants

(a) If a newborn is transferred to another in-State birthing facility, the receiving facility shall conduct newborn hearing screening in accordance with this subchapter.

(b) If a newborn is transferred to another in-State non-birthing facility, the birthing facility of birth shall conduct newborn hearing screening in accordance with this subchapter prior to transfer, or to ensure that a hearing screening is performed by one month of age or as soon as the newborn is medically cleared.

(c) Birthing facilities shall include Newborn Hearing Follow-up Reports in medical records of infants transferred to out-of-State health care facilities prior to transfer to encourage these out-of-State health care facilities to forward hearing screening and/or diagnostic audiologic evaluation results to the New Jersey Early Hearing Detection and Intervention Program.

8:19-1.5 Screening/testing personnel

(a) Each birthing facility shall designate a licensed audiologist or physician who shall oversee the birthing facility's newborn hearing screening program and who shall ensure the implementation of the following:

1. Training and supervision of the individuals performing the screening in accordance with (b) and (c) below;
2. Recording of screening results;
3. Reporting EBC data ;
4. Educating and Counseling parents;
5. Developing effective strategies for communicating the hearing screening results to parents and responsible physicians;

6. Coordinating follow-up services including referrals for re-screening or diagnostic evaluation as appropriate; and
7. Annually reviewing policies and procedures.

(b) Only licensed audiologists or physicians, or other examiners under the direction and supervision of either licensed audiologists or physicians, shall conduct newborn hearing screening in accordance with the requirements of this subchapter.

1. All personnel who conduct newborn hearing screening shall undergo an annual competency evaluation on their screening administration and documentation skills as well as adherence to infection control procedures.

(c) All personnel performing newborn hearing screening shall be supervised and trained in the performance of newborn hearing screening. Training shall include the following:

1. The performance of newborn hearing screening;
2. Infection control practices;
3. The general care and handling of newborns in hospital settings according to established hospital policies and procedures;
4. The documentation of screening results as directed; and
5. Maintenance confidentiality of records.

(d) If after the conduct of screening, further diagnostic testing is indicated by the JCIH Position Statement, the diagnostic testing shall be conducted by either a licensed audiologist or physician.

(e) The facility shall notify the Department when personnel providing oversight of the newborn hearing program change.

8:19-1.6 Reporting by means of the Electronic Birth Certificate

(a) For each live newborn born at, or transferred to a birthing facility that has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System, the birthing facility shall report, within one week of the newborn's discharge or transfer, the EBC fields or information identified below to the Department by means of the Electronic Birth Certificate Registration System in the manner prescribed by the State Registrar of Vital Statistics for the submission of EBCs:

1. The mother's first name;
2. The mother's last name;
3. The child's first name;
4. The child's last name;
5. Sex;
6. Race;
7. Primary language;
8. Hearing test results for each ear;
9. The screening methodology used for each ear;
10. The date of testing each ear;
11. Initial screening vs. rescreening indicator;

12. Indicator if referral was made for audiologic follow-up;
13. The name of the provider to whom referral was made, if applicable; and
14. Indicators for risk factors (family history of hearing loss, TORCH, congenital syphilis, persistent pulmonary hypertension, stigmata/syndromes associated with hearing loss, hyperbilirubinemia, meningitis, exchange transfusion, ECMO, ototoxic medication, days of mechanical ventilation, one and five minute Apgar scores, birthweight, NICU admission and discharge dates).

(b) For each live newborn born outside a birthing facility, such as at home, who subsequently is transferred to a birthing facility, the receiving facility shall ensure the report required in (a) above is made, if the receiving facility has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System.

(c) For each newborn transferred to another in-State birthing facility, the sending facility shall complete an EBC transfer abstract within one week of the transfer and shall send the abstract to the receiving facility, if the sending facility has elected to participate in the submission of birth certificates by means of Electronic Birth Certificate Registration System.

8:19-1.7 Exemption from testing

(a) This subchapter shall not apply in the case of any newborn whose parent objects to the hearing screening on the grounds that screening would conflict with the parents' bona fide religious tenets or practices.

(b) In case of refusal to screening pursuant to (a) above, the birthing facility, or, in the event of a home birth the physician or attending midwife, shall ensure that documentation of refusal to have the newborn's hearing screened is signed by the parent, becomes part of the infant's permanent medical record, and if the birth occurs at a birthing facility that has elected to participate in the submission of birth certificates electronically by means of the Electronic Birth Certificate Registration System, is documented in the EBC.

8:19-1.8 High-risk indicators

(a) The JCIH Position Statement identifies risk factors that require periodic audiologic monitoring to detect progressive or late onset hearing loss. Upon receipt of the notice required in N.J.A.C. 8:19-1.9(f)1 of the presence of these risk factors, the infant's responsible physician shall ensure the monitoring of these infants in accordance with the time intervals and other protocols identified in the JCIH Position Statement.

(b) Birthing facilities that treat infants and children up to the age of three with ototoxic medications shall ensure baseline hearing assessment prior to administration of drug therapy unless medically contraindicated, as well as throughout and following the course of treatment in accordance with the birthing

facility's ototoxic drug monitoring procedures, established pursuant to N.J.A.C. 8:19-1.3(c)11.

(c) If risk factors for late onset hearing loss are identified after discharge from the birthing facility and at any time up to the age of three, the responsible physician and any audiologist who may have seen the child, who have identified the presence of the risk factors shall report the risk factors to the Department by means of the Newborn Hearing Follow-Up Report, and advise the parents of the need to have an audiologic evaluation, as well as audiologic monitoring at intervals as defined by the current JCIH Position Statement.

1. Audiologists who identify the presence of a risk factor for late onset hearing loss shall inform the child's medical home of this condition and the need for follow-up.
2. Once informed of the newly identified risk factor for late onset hearing loss, the medical home shall be responsible for advising parents of the importance of children under the age of three receiving audiologic monitoring in accordance with JCIH Position Statement.

8:19-1.9 Hearing screening follow-up

(a) If a physiological hearing screening measure is performed on both ears of an infant prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician of the results by written documentation; and
2. Notify the parent of the results via face-to-face communication along with written documentation.

(b) If a physiological hearing screening measure is not performed on one or both ears of an infant prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation;
2. Notify and counsel the parent via face-to-face communication along with written documentation of the need for a follow-up hearing screening by a licensed audiologist, licensed physician, or other examiners under their direction and/or supervision; and
3. Provide parents with a Newborn Hearing Follow-up Report form with the demographic information completed (see N.J.A.C. 8:19-1.10(e)).

(c) If an infant does not pass the physiological hearing screening measure on both ears prior to discharge, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation;
2. Notify and counsel the parent via face-to-face communication along with written documentation of the need for a follow-up hearing screening or diagnostic testing by a licensed audiologist, licensed physician, or other examiners under their direction and/or supervision; and

3. Provide parents with a Newborn Hearing Follow-up Report form with the demographic information completed (see N.J.A.C. 8:19-1.10(a)).

(d) If additional outpatient screening is required, the parent shall be advised of the need for screening to be performed by one month of age.

(e) If outpatient diagnostic audiologic testing is required, the parent shall be advised of the need for testing to be performed by three months of age.

(f) If an infant presents with risk indicators associated with hearing loss as identified in the JCIH Position Statement, then, prior to the infant's discharge home, the birthing facility shall:

1. Notify the responsible physician by written documentation;
2. Notify the parents via face-to-face communication along with written documentation of the risk indicator(s) present;
3. Provide parents with a Newborn Hearing Follow-up Report form with the demographic information completed; and
4. Counsel parents to monitor their infant's hearing according to the current JCIH position statement.

(g) The hospital or birthing center shall provide parents with information for referrals to centers such as audiology and otolaryngology providers that perform diagnostic pediatric audiologic testing.

(h) If an infant does not pass or receive a physiological hearing screening measure on both ears prior to discharge, the birthing facility shall ensure that the infant receives follow-up services by making at least two documented attempts to

remind families who are in need of follow-up either by United States Postal Service or by telephone, excluding busy signals or no answer.

(i) Diagnostic testing must yield ear-specific information, a statement regarding the type and degree of hearing loss in each affected ear, and recommendation for medical and habilitative services.

8:19-1.10 Reporting newborn hearing follow-up

(a) A licensed audiologist, physician, or other examiner under the direction and/or supervision of an audiologist or physician, who conducts outpatient screening or testing for the reasons identified in (a) 1and 2 below, shall complete the Newborn Hearing Follow-up Report form, submit the completed form to the Department, and report the results to the infant's medical home within 10 days of the conduct of the outpatient screening or testing.

1. In accordance with discharge instructions provided pursuant to N.J.A.C. 87:19-1.9; or
2. For infants that present with risk indicators for late onset hearing loss as identified in the JCIH Position Statement.

(b) The requirements of (a) above for submission of a Newborn Hearing Follow-up Report form to the Department and the report to the medical home apply for each screening or testing as may be administered in accordance with the JCIH Position Statement protocols for re-examination at regular intervals.

(c) Newborn Hearing Follow-up Report forms shall be completed with ear specific results for all children receiving outpatient screening or audiologic evaluation. Documentation of a “Pass” result in the Recommendations section of the Newborn Hearing Follow-up Report form can only be considered if screening or audiologic measures indicate:

1. A pass result on either DPOAE or TEOAE screening for each ear;
2. A pass ABR screening (with screening intensity levels at or below 35dBHL); or
3. Ear specific behavioral responses better than 30dBnHL in the speech frequency range (500 to 4,000 hertz).

(d) Confirmation of hearing status shall be obtained within one month but no later than three months after initial screening.

(e) If a newborn is not screened due to birth outside a hospital or birthing center, such as at home, and is not transferred to a hospital or birthing center, the baby shall be screened with physiological measures prior to one month of age. The physician or midwife shall advise the parent of the importance of newborn hearing screening, complete and submit to the Department the Newborn Hearing Follow-up Report form if screening and/or testing were performed in the physician’s office within 10 business days of the screening and/or testing.

(f) The following procedures are considered inappropriate for children undergoing initial or repeat screening:

1. Non-calibrated signals, such as rattles, music boxes, noisemakers;

2. Non-conditioned behavioral procedures, such as behavioral observation audiometry;
3. Signals that lack frequency specificity, such as music, broadband noise;
4. Speech stimuli in lieu of frequency specific stimuli;
5. Use of soundfield studies in isolation (without inclusion of ear specific data); or
6. Use of “age-appropriate” response criteria to define presence of hearing loss, unless minimal intensity levels necessary to elicit auditory responses are below 30 dBHL in each ear in the frequency region important for speech recognition and comprehension (500 to 4,000 hertz).

(g) In the following situations, a birthing facility, audiologist, physician, or other examiner under the direction and/or supervision of an audiologist or physician, with follow-up responsibilities under this subchapter, shall submit a Newborn Hearing Lost to Follow-up Report form to the Department and to the medical home:

1. Missed outpatient follow-up appointment;
2. Unable to make reminder contact (disconnected phone or returned mail);
3. Infant who is known to have moved out of State;
4. To report the name and address of the facility where newborn is being treated when treated out of State;
5. Documentation of two unsuccessful attempts to contact family for follow-up;
6. Family refusal to return for follow-up; or

7. Determination that a previously identified risk factor condition has been ruled out at follow-up visit.

8:19-1.11 Documenting and reporting a diagnosed hearing loss

(a) When a permanent hearing loss is confirmed, the person completing the Newborn Hearing Follow-up Report shall register the child through 21 years of age with the Special Child Health Services Registry by submitting a completed Special Child Health Services Registration form to the Department as soon as possible after diagnosis, which shall include specification in the “diagnosis” section of the form, of the type and degree of hearing loss, the affected ears, and, if known, the syndrome related to the child’s hearing loss.

(b) When a permanent hearing loss is confirmed, the audiologist shall inform the responsible physician by written documentation and parents via face-to-face communication and written documentation of the type and degree of hearing loss.

(c) Infants born with external auditory canal atresia shall be registered as such, prior to discharge from the birthing facility. By definition, these children present with hearing loss and should be afforded the opportunity to engage in Early Intervention Services. Bone conduction ABR studies should be performed prior to three months of age to determine the cochlear status of the affected ear(s).

(d) If a diagnosis of hearing loss is made, the responsible physician shall advise the parents of the importance of an otolaryngologic, genetic and ophthalmologic

evaluation to be completed by three months post diagnosis, for additional diagnostic assessment regarding the etiology of the hearing loss. In addition, the responsible physician shall advise the parents of the importance of ongoing audiologic reevaluation to monitor hearing status and the performance of prescribed devices such as hearing aids or cochlear implants. Responsible physicians shall also register children diagnosed with permanent hearing loss (through 21 years of age) with the Special Child Health Services Registry.

(e) Updated Special Child Health Registration forms shall be submitted to the Department if additional information is discovered at follow-up audiologic visits regarding changes in hearing status; confirmatory diagnosis of a syndromic condition; additional documented physical disabilities, and/or change in name, address or parent.

8:19-1.12 Central newborn hearing registry

Special Child Health and Early Intervention Services shall establish and maintain a central registry of newborns identified as having or being at risk of developing a hearing loss. The information in the central registry shall be used for the purposes of compiling statistical information and providing follow-up counseling, intervention and educational services to the parents of the newborns listed in the registry.

8:19-1.13 Confidentiality of reports

The reports made are to be used only by the Department and such other agencies as may be designated by the Commissioner and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom they relate; and to that end, such reports shall be deemed “information relating to medical history, diagnosis, treatment or evaluation” within the meaning of Executive Order 26, § 4b1 (McGreevey 2002), and, therefore, not “government records” subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., particularly 1A-1.1”.

8:19-1.14 Non-liability for divulging confidential information

No individual or organization providing information to the Department for the purpose of the Newborn Hearing Screening Program shall be deemed to be, or held liable for, divulging confidential information.